Performance of the HandScan in tight control treatment of rheumatoid arthritis

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29197

Source
Nationaal Trial Register

Health condition

Rheumatoid arthritis

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: LSH Impuls

Intervention

Outcome measures

Primary outcome

Health Assessment Questionnaire (HAQ)

Secondary outcome

Swollen joint count (monthly)

Tender joint count (monthly)

C-reactive protein (monthly)

VAS general health (monthly)

HandScan score (monthly)

The health survey SF36

EQ5D

Questionnaire on direct and indirect costs.

Study description

Background summary

Rationale: The treatment of rheumatoid arthritis (RA) has significantly been improved over the past years due to earlier and more intensive treatment including the use of biologicals. Due to the demanding approach, the principle of this tight control treatment and treat-to-target early in the disease has not been adequately implemented in standard rheumatology care yet.
Recently, the HandScan has been developed, to objectively assess disease activity in RA patients in only 1.5 minutes. Our hypothesis is that clinical efficacy of HandScan remission guided treatment is at least as good as and more cost-effective than the conventional ACR/EULAR remission guided treatment. This makes this novel imaging technology more cost-effective allowing implementation in standard rheumatology care.

Objective: Primary: to compare improvement on the Health Assessment Questionnaire (HAQ) between HandScan guided tight control in combination with treat-to-target treatment and the conventional ACR/EULAR remission guided tight control in combination with treat-to-target treatment of RA after 1 ½ years. Secondary: to compare cost effectiveness of both arms, based on customized cost questionnaires. Tertiary: to evaluate radiographic joint damage based on a fully automated radiographic scoring of the hand joints as well as the Sharp van der Heijde score in both study arms.

Study design: Randomized controlled trial comparing the ACR/EULAR remission criteria guided treatment with the HandScan remission guided treatment in rheumatoid arthritis.
Study population: Patients (n=112; ≥18 years) with recently diagnosed RA (DMARD naïve, no significant visual deformations of hand or fingers)
Intervention (if applicable): In both treatment strategy arms patients will be treated with a Methotrexate (MTX)-based tight control strategy (10 mg/wk) with prednisone (10 mg/day). If patients do not reach remission based on EULAR or HandScan predefined criteria, the strategy will be intensified monthly according to predefined steps. If remission has been reached, the treatment will be continued at the same medication level and eventually

decreased.

Main study parameters/endpoints: the Health Assessment Questionnaire (HAQ)

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: All included patients visit the outpatient clinic every month to assess disease activity as needed for the tight control strategy in clinical practice. At baseline, 3 months, 6, 12, and 18 months, patients are asked to fill in the Health Assessment Questionnaire (HAQ; 1st outcome), the health survey SF36, EQ5D and the questionnaire on direct and indirect costs.
Radiographs of hand and feet are taken at baseline and at 18 months according to clinical practice. Since the HandScan guided treatment is novel, treatment strategy decision may in theory deviate too much from proven standard tight control care leading to undesired over- or under treatment. This will be monitored extensively during the study and the treatment strategy will be adjusted if needed.

Study objective

Clinical efficacy of the HandScan guided treatment is at least as good and more cost-effective than the conventional DAS guided treatment.

Study design

Baseline and monthly visits during 18 months.

Questionnaires are taken at baseline, 3 months, 6 months, 12 months and 18 months.

Intervention

HandScan guided treatment strategy or conventional ACR/EULAR remission criteria guided treatment strategy. In both treatment strategy arms patients will be treated with a Methotrexate (MTX)-based tight control strategy (10 mg/wk) with prednisone (10 mg/day). If patients do not reach remission based on EULAR or HandScan predefined criteria, the strategy will be intensified monthly according to predefined steps. If remission has been reached, the treatment will be continued at the same medication level and eventually decreased.

Contacts

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Eligibility criteria

Inclusion criteria

• Male or non-pregnant, non-nursing female

• ≥ 18 years of age

• Early RA patients, fulfilling 2010 ACR/EULAR criteria: Evidence of clinically apparent arthritis < 1y as assessed by a rheumatologist

• Patients able and willing to give written informed consent and comply with the requirements of the study protocol

Exclusion criteria

• Significant visual deformations of hands or fingers

Other (joint) disease

• Rheumatic autoimmune disease other than RA

• Current inflammatory joint disease other than RA (e.g. gout, reactive arthritis, psoriatic arthritis, seronegative spondyloarthropathy, Lyme disease)

• Known porphyria (HandScan risk analysis).

Drug-specific

• Contraindication for methotrexate or prednisolone

• Glucocorticoids used for RA < 6 weeks prior to baseline (NB: inhaled glucocorticoids are

allowed)

• Previous treatment with any DMARD that is used in the treatment of RA

• Previous treatment with any biological drug that is used in the treatment of RA

• Treatment with any investigational agent within 4 weeks (or 5 half-lives of investigational agent, whichever is longer) before screening.

• Patients using photodynamic therapy medication (HandScan risk analysis).

General medical

• History of alcohol, drug, or chemical abuse within the 6 months prior to screening. Alcohol abuse is defined as more than 3 units per day.

• Neuropathies or other painful conditions that might interfere with pain evaluation

• Psychological or intellectual disorders that impede to participate in the study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-04-2017
Enrollment:	112
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-04-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47182
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6216
NTR-old	NTR6388
CCMO	NL50026.041.14
OMON	NL-OMON47182

Study results